DUKE UNDERGRADUATES ENGAGED IN THE CONSENT PROCESS ON DUHS IRB PROTOCOLS

11/20/2023

Duke undergraduate students (work-study, unpaid, or engaged in research for class credit) may conduct the informed consent process in accordance with the following policy:

- ***Duke undergraduate students at least 18 years of age may conduct the informed consent process, but only on a limited scope of studies.*** Currently enrolled Duke undergraduate students would be allowed to conduct the informed consent process on the following types of studies:
    - Studies with no more than minimal risk
    - Other studies deemed appropriate by IRB at the time of review

- ***Documentation of Undergraduate Student Training.*** Prior to being approved to conduct the informed consent process, students will have completed the following training which must be documented and retained by the study team:
    - CITI modules as defined by the DUHS IRB
    - All specific Duke Office of Clinical Research (DOCR) training involving the informed consent process
    - Complete the DOCR Undergraduate Consenting Competency Checklist with their supervisor from the study team, and return the completed checklist to docr.help@dm.duke.edu to be included in the undergraduate's LMS training record.
    - Students who are not being paid are considered volunteers and therefore must adhere to the "Volunteer & Unpaid Intern Policy Guidelines". Prior to adding the student to the research protocol, the study team must follow the DUHS IRB's process for adding unpaid volunteers to study personnel, which includes completion of the Volunteer Agreement Letter, and uploading necessary documents into the iRIS key personnel amendment. Documentation of completed training should be maintained in the regulatory binder and the undergraduate student should be added to Delegation of Authority Log.

- ***Oversight for studies allowing undergraduate student consent.*** Duke Undergraduate students must have oversight on several levels:

- Studies that involve undergraduates in the consent process must be conducted under the oversight of an approved CRU or Oversight Organization.
- A Duke Faculty/staff member must be responsible for ongoing monitoring of the informed consent process conducted by the Duke undergraduate student, which must include regularly “shadowing” and reviewing the consent documentation practices of the Duke undergraduate student. Documentation of the shadowing will be placed in the study’s regulatory binder.
- When an undergraduate student is added to a study protocol as Key Personnel, the original application or personnel amendment must include the name of the Duke Faculty/staff member who will train the student on conducting the study-specific consent process. This Duke Faculty/staff member must have taken the DOCR informed consent training, be listed as Key Personnel on the iRIS application, and be listed on the Delegation of Authority Log. This person will document that the student is competent to obtain consent from study participants; that documentation will be placed in the study’s regulatory binder.
- If the study involves recruitment from the Duke Health patient pool, a Duke Faculty/staff member must be responsible for associating the enrolled study participant in Maestro Care in accordance with DOCR’s policy on “Registration of Clinical Research Participants Who Provide Informed Consent**”.**

Previous Version Date(s): 9/16/2015, 11/17/2015, 3/4/2016, 11/29/2017, 5/6/2020, 2/8/2021